IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,

:

: Criminal No. 2:20-cr-200-RBS

TEVA PHARMACEUTICALS USA, INC. and GLENMARK PHARMACEUTICALS

INC., USA,

v.

Defendants. :

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S MOTION FOR DISCLOSURE OF EVIDENCE PRESENTED TO THE GRAND JURY AS TO "OTHER GENERIC DRUGS"

I. INTRODUCTION

In August 2020, the Grand Jury returned the Second Superseding Indictment ("SSI"), charging Teva Pharmaceuticals USA, Inc. ("Teva") with three counts of conspiracy to restrain trade in violation of the Sherman Act. Each count alleges that Teva conspired with <u>different</u> competing pharmaceutical manufacturers, about <u>different</u> generic drugs, using <u>different</u> forms of supposed anti-competitive conduct. The SSI explicitly alleges three different conspiracies in three distinct counts. The three counts in the SSI name five separate conspirators and eleven generic drugs that were the subject of alleged agreements to fix prices, rig bids, or allocate customers.

The allegations in each count of the SSI are narrow and specific as to the nature of each alleged conspiracy. Nonetheless, the government has now informed Teva that, at trial, it intends to expand upon the allegations in the SSI both by asserting the existence of conspiracies the Grand Jury did not charge in the SSI and by attempting to prove that Teva conspired to restrain trade for specific drugs the SSI never mentions.

But to prosecute an antitrust conspiracy against Teva, the government must identify the scope of the conspiracy. This includes defining the product market or markets (*i.e.*, the specific drugs) that the alleged conspirators agreed to manipulate. Furthermore, the Constitution requires that "[n]o person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury." U.S. Const. Amend. V. "A court cannot permit a defendant to be tried on charges that are not made in the indictment against him." *Stirone v. United States*, 361 U.S. 212, 217 (1960).

The government's conduct here—including its apparent intent to introduce evidence at trial as to conspiracies not charged, and drugs not referenced, in the SSI—suggests significant irregularities in the grand jury process, such that the SSI may be subject to a motion to dismiss in full or in part. Accordingly, and for two distinct but related reasons, Teva has a particularized

need to review a narrow slice of the evidence the government presented to the Grand Jury concerning the alleged generic drugs that the government asserts were the subject of each of these distinct conspiracies but were not identified in the SSI. First, Teva needs access to these limited materials to determine the appropriateness of a motion to dismiss the SSI for failing to allege sufficiently the market or markets that were supposedly the subject of a wrongful agreement. Second, given the government's planned deviation from the SSI, it is likely that the government intends to try Teva for crimes that the government never actually presented to the Grand Jury.

The interests of justice supporting Teva's narrow request for disclosure far outweigh any competing concerns with grand jury secrecy. Teva is not on a fishing expedition seeking access to irrelevant Grand Jury transcripts. Nor is Teva seeking to learn the identity of any witness who testified before the Grand Jury. Moreover, there is no reason to believe that the Grand Jury is still investigating Teva long after any applicable statute of limitations period has ended.

II. FACTUAL BACKGROUND

A. The SSI and the Three Alleged Conspiracies

On August 25, 2020, the Grand Jury returned the three-count SSI, naming Teva as a defendant for the first time. ECF No. 28. The SSI alleged three separate conspiracies to engage in anticompetitive activity. Count One charges Teva with conspiring with Glenmark Pharmaceuticals Inc., USA ("Glenmark") and Apotex Corp. ("Apotex") "to increase and maintain prices of pravastatin and **other generic drugs** sold in the United States." *Id.* at ¶ 20 (emphasis added). Count Two charges Teva with conspiring with Taro Pharmaceuticals U.S.A., Inc. ("Taro") "to allocate customers and rig bids for, and stabilize, maintain, and fix prices of" the generic drugs carbamazepine, clotrimazole, etodolac IR and ER, fluocinonide, and warfarin, "**among others**." *Id.* at ¶¶ 36, 39 (emphasis added). Finally, Count Three charges Teva with conspiring with Sandoz Inc. (Sandoz") "to allocate customers and rig bids for, and to stabilize, maintain, and fix prices of"

the generic drugs etodolac IR, nadolol, temozolomide, and tobramycin, "**among others**." *Id.* at ¶¶ 48, 53 (emphasis added).

Importantly, the SSI alleges Teva engaged in different anti-competitive conduct relating to different specific drugs. For example, with regard to pravastatin, in Count One the SSI alleges that Teva, Glenmark, and Apotex coordinated to increase the drug's price, but with regard to tobramycin, in Count Three it alleges that Teva and Sandoz reached an agreement to allocate customers among the two companies. *Id.* at ¶¶ 22–25, 51.

B. The Government Informs Teva That It Will Seek to Prove the Charged Conspiracies Involved Many More Drugs than Those Charged in the SSI

To date, the government has produced more than 23 million records to Teva in discovery. The SSI's vague references to "other" drugs dramatically increased the significant time and expense necessary to review this extraordinary volume of discovery. Thus, on April 14, 2021, Teva wrote the government requesting confirmation that the conspiracies alleged in Counts One, Two, and Three "only concern the generic drugs specifically named in each of those respective counts." *See* Exhibit 1 at 2. Far from giving that confirmation, the government replied on April 27, 2021 disclosing a list of twenty-one additional drugs ("newly identified drugs") not identified in the SSI that the government said were the subject of the three conspiracies alleged in the SSI. *See* Exhibit 2 at 2.1 And despite providing this list of nearly two dozen new drugs, the government advised that its evidence is still "not limited to" the now over thirty drugs either identified in the

The drugs named in the April 27, 2021 letter not identified in the SSI include: adapalene gel, fluconazole, levocetirizine, moexipril, nabumetone, ondansetron, and ranitidine for Count One; adapalene gel, enalapril, ketoconazole cream, and nortriptyline for Count Two; and amiloride, bumetanide, clemastine, dicloxacillin, fluocinonide, hydralazine, ketoconazole cream, labetalol, nabumetone, and triazolam for Count Three. It is confounding that, during more than twenty interviews with its cooperating witness, the government did not even ask about some of the newly identified drugs that the government claims were the subject of the conspiracies.

SSI or the April 27, 2021 letter, suggesting that the government could later decide that the conspiracies involved yet additional drugs, above and beyond the thirty already identified. This expansion of the set of potentially relevant drugs is especially concerning for Teva since during the relevant period identified in the SSI Teva sold more than 400 generic drug-formulations.

On July 6, 2021, Teva wrote the government again, requesting that it "produce any and all grand jury transcripts that relate to the unnamed 'other' generic drugs referenced in each of the three counts of the [SSI]." *See* Exhibit 3 at 1. Teva's letter advised that "the [government]'s vague statement that it 'may also introduce evidence relating to the other [twenty-one] drugs to further establish the existence of the charged conspiracies and the relationship between the coconspirators' is insufficient to provide Teva with appropriate information as to how evidence relating to those drugs may ultimately be used at trial." *Id.* That is particularly true given that the government has produced over 23 million documents in discovery.

On August 6, 2021, the government responded, refusing to disclose any grand jury evidence or other materials and asserting both that "the [SSI] clearly charged conduct beyond the specifically named drugs" and that identifying twenty-one additional drugs "did not expand the scope of the [SSI]." *See* Exhibit 4. The government further said, "[t]o the extent grand jury transcripts contain material that is discoverable, they will be produced pursuant to district practice." *Id.* While there is no written district practice concerning the production of grand jury transcripts in the Eastern District of Pennsylvania, the United States Attorney's Office typically produces transcripts of witness testimony before the grand jury. Nonetheless, here the government has persisted in its refusal to produce these transcripts.

C. The Government Tells Teva It Will Assert Conspiracies Not Charged in the SSI

On July 1, 2021, Glenmark filed a Motion for Misjoinder and Severance, arguing that Count One should be severed from the other Counts because "[i]t would be unduly burdensome

and prejudicial to subject Glenmark to a joint trial . . . in which the majority of proof would relate to Counts Two and Three rather than the charge against Glenmark." ECF No. 105 at 1. In opposing this motion, the government argued: (a) the conspiracy charged in Count One overlapped with the conspiracy charged in Count Two because Teva and Glenmark executives conspired to restrain trade in the drug adapalene, and then Teva and Taro executives also conspired to restrain trade in adapalene; and (b) the conspiracy charged in Count One overlapped with the conspiracy charged in Count Three because Teva and Glenmark executives conspired to restrain trade in the drug nabumetone, and then Teva and Taro executives also conspired to restrain trade in nabumetone. ECF No. 116 at 5. Importantly, however, these "newly identified conspiracies" do not appear anywhere in the SSI. The government effectively proffered that Teva was at the center of a hub-and-spoke conspiracy even though the SSI alleges no such thing. No Count in the SSI even mentions the drugs adapalene or nabumetone.

On February 1, 2022, Glenmark filed a Motion for Limited Disclosure of Evidence Presented to the Grand Jury as to "Other Generic Drugs" ("Glenmark's Grand Jury Motion"). That motion sought "disclosure or inspection of the specific portions of any testimony or exhibit actually presented to the Grand Jury about generic drugs other than pravastatin with respect to Glenmark and Count One" or, in the alternative, *in camera* inspection of such materials. ECF No. 148 at 2. While seeking similar relief, Glenmark's motion differs from this motion because Glenmark is only named as a defendant in Count One and therefore seeks disclosure of the Grand Jury evidence relevant to "other generic drugs" to fairly assess whether any evidence of other drugs actually concerned the single Count in which it is charged.

III. <u>LEGAL STANDARD</u>

The Grand Jury Clause of the Fifth Amendment establishes that "[n]o person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury." U.S. Const. Amend. V. The grand jury determines "whether there is probable cause to believe a crime has been committed" and protects "citizens against unfounded criminal prosecutions." *United States v. Calandra*, 414 U.S. 338, 343 (1974). "A court cannot permit a defendant to be tried on charges that are not made in the indictment against him." *Stirone v. United States*, 361 U.S. 212, 217 (1960).

Under Federal Rule of Criminal Procedure Rule 6(e)(3)(E)(ii), a court may order disclosure of grand jury materials "at the request of a defendant who shows that a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury." A defendant seeking disclosure of grand jury information must show "a particularized need for that information which outweighs the public interest in secrecy." *United States v. McDowell*, 888 F.2d 285, 289 (3d Cir. 1989) (citing *United States v. Proctor & Gamble Co.*, 356 U.S. 677, 683 (1958)). In discussing the policy interests supporting grand jury secrecy, the Supreme Court has written:

First, if preindictment proceedings were made public, many prospective witnesses would be hesitant to come forward voluntarily, knowing that those against whom they testify would be aware of that testimony. Moreover, witnesses who appeared before the grand jury would be less likely to testify fully and frankly, as they would be open to retribution as well as to inducements. There also would be the risk that those about to be indicted would flee, or would try to influence individual grand jurors to vote against indictment. Finally, by preserving the secrecy of the proceedings, we assure that persons who are accused but exonerated by the grand jury will not be held up to public ridicule."

Douglas Oil Co. v. Petrol Stops Nw., 441 U.S. 211, 222 (1979).

"The defendant's request for disclosure must be 'structured to cover only material so needed." *United States v. Chalker*, Crim. Action No. 12-0367, 2013 U.S. Dist. LEXIS 122018, at *14 (E.D. Pa. Aug. 27, 2013) (Surrick, J.) (quoting *In re Grand Jury Matter (Catania)*, 682 F.2d

61, 62 (3d Cir. 1982)). Following a showing of particularized need, the Court "must weigh the competing interests and order so much disclosure as needed for the ends of justice." *Id.* (quoting *Catania*, 682 F.2d at 62).

IV. ARGUMENT

The government has obtained an indictment charging Teva with three counts of conspiracy to restrain trade in violation of the Sherman Act. The SSI alleges three distinct conspiracies, each involving different co-conspirators, different drugs, and different forms of anti-competitive conduct, including price fixing and bid rigging. Despite the clear and limited language of that indictment, the government has now added nearly two dozen additional drugs found nowhere in the SSI which it contends were the subject of these same conspiracies. The government also claims that rather than three distinct conspiracies as charged in the SSI, it now apparently intends to try to prove one overarching hub-and-spoke conspiracy with Teva as its center.

As a result, Teva has a particularized need for disclosure of the evidence the government presented to the Grand Jury concerning the scope of the charged conspiracies and the specific drugs that were the subject of the charged conspiracies. Given the government's intention to deviate from the text of the SSI, Teva is entitled to determine if the Grand Jury properly charged Teva with antitrust conspiracies involving those drugs. A fair balancing of the competing interests plainly favors Teva's narrow request for disclosure of evidence presented to the Grand Jury on this specific issue. Of course, should this Court feel it more appropriate, it may examine the relevant Grand Jury evidence *in camera*. Either way, Teva has articulated a particularized need, pursuant to Rule 6(e)(3)(E)(ii), justifying the opportunity to assess whether the government is attempting to try Teva for crimes that it never actually presented to the Grand Jury.

A. Teva Has a Particularized Need for Disclosure of Evidence Presented to the Grand Jury Concerning "Other Generic Drugs"

The government contends that the SSI's inclusion of the phrases "among other drugs" and "other generic drugs" means that it can assert, at trial, that Teva conspired to restrain trade for any drug the government decides to include in its trial presentation. That is not the law.

Charging a defendant with conspiracy to restrain trade in violation of the Sherman Act requires alleging a wrongful agreement to manipulate a market for a specific good or service. "An agreement 'to rig bids wherever and whenever possible' is meaningless for Sherman Act purposes unless there are in the real world of the marketplace some 'whens' and 'wheres." *United States v. Sargent Elec. Co.*, 785 F.2d 1123, 1127 (3d Cir. 1986). As such, an alleged agreement is insufficient if it fails to identify the market that has been unlawfully manipulated. *Queen City Pizza v. Domino's Pizza*, 124 F.3d 430, 435 (3d Cir. 1997).²

Appropriate product markets are defined by the interchangeability of the items that comprise them. For instance, one could conceive of a conspiracy to fix prices for certain kinds of cars, but a conspiracy to fix the prices of all vehicles (including vehicles that don't actually compete with one another) would make no sense. Drugs are no different. Drugs used to treat entirely different conditions cannot logically be considered interchangeable. To that end, courts examining this issue in the context of drugs often limit those product markets to a single molecule (a brand name drug and its generic alternative) or at most to drugs used in the same therapeutic area. *See, e.g., Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 436 (3d Cir. 2016); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013).

² Cases interpreting Section One of the Sherman Act in the civil context are equally applicable in the criminal context. *United States v. Nippon Paper Indus. Co.*, 109 F.3d 1, 4 (1st Cir. 1997) (noting while interpreting Section One of the Sherman Act that "courts should interpret the same language in the same section of the same statute uniformly, regardless of whether the impetus for interpretation is criminal or civil").

The fact that the government has alleged a *per se* violation of the Sherman Act does not alter the analysis. The Third Circuit has made clear that "while the *per se* rule proscribes inquiry into competitive effects, **it does not excuse identification of relevant markets**." *United States v. Sargent Elec. Co.*, 785 F.2d 1123, 1127 (3d Cir. 1986) (emphasis added). And the Third Circuit emphasized the point by noting the specific challenges that market definition poses in drafting criminal antitrust indictments: "[b]ecause Sherman Act conspiracies involve a relevant market and that market may vary over time, the government's task in drafting indictments is somewhat more complex than in other conspiracy contexts." *Id.*

The government seeks to turn this well-established antitrust law on its head. The government apparently believes that because, for instance in Count One, the SSI alleges a conspiracy to restrain trade for the drug pravastatin, it can allege that this conspiracy extended to undefined "other generic drugs" without identifying those drugs for the Grand Jury. This effectively eliminates the government's obligation to define a relevant market.

The government's "theory" suggests that the grand jury process resulting in the SSI likely suffered from one of two problems. It may be that the government never introduced evidence of some or all of the newly identified drugs that it now asserts are part of the "other generic drugs" identified in Counts I–III and thus failed to identify the relevant markets in which Teva allegedly restrained trade. This would serve to invalidate the indictment, in whole or in part. *See United States v. Williams*, No. 4:08-cr-00070, 2013 U.S. Dist. LEXIS 45323, at *32 (M.D. Pa. Mar. 29, 2013) ("It is simply well-established law . . . that elements of a crime should be submitted to the grand jury") (quoting *United States v. LeCroy*, 441 F.3d 914, 921 (11th Cir. 2006)).

Alternatively, the grand jury evidence may show that the government believes, incorrectly, that the relevant market can include numerous generic drugs that treat entirely different ailments.

But then the government's proposed relevant market would be grossly overbroad, and the SSI would be infirm for that entirely different reason. Again, product markets for antitrust purposes include "those 'commodities reasonably interchangeable by consumers for the same purposes." *Fineman v. Armstrong World Indus.*, 980 F.2d 171, 198 (3d Cir. 1992) (quoting *United States v. E.I. Du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956)). Courts consider "price, use and qualities" as factors in determining the interchangeability of products in a relevant market. *Id.* (quoting *Du Pont de Nemours*, 351 U.S. at 404). Generic drugs used to treat entirely different medical conditions cannot reasonably be considered interchangeable. For example, if a consumer were looking for pravastatin to treat a high cholesterol problem, carbamazepine—a drug used to treat seizures—could not under any circumstance be considered an acceptable alternative.

Teva's concern is not unique. Antitrust litigants routinely (and often successfully) argue that an alleged antitrust violation in the pharmaceutical industry is deficiently pled because it fails to define an appropriate relevant market. Courts facing this issue have at times accepted product markets consisting of only a branded drug, a branded drug and its generic substitutes, or competing drugs used to treat a similar condition. No court has ever accepted a product market for antitrust purposes as broad as the conspiracy the government seems to be claiming existed here.

For example, in *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978), the Third Circuit made clear that defining a product market to include a wide array of different drugs—as the government seeks to do here—is inappropriate and untenable. The question in *SmithKline Corp.* was whether the defined relevant market could include an antibiotic called cephalosporins and antibiotics used to treat different infections. The Court examined the differences and similarities between the two groups of products to determine the scope of "the market where there is true economic rivalry because of product similarity." *Id.* at 1065. The Court rejected the

defendant's effort to define a product market consisting of all antibiotics because "there is neither appropriate interchangeability, price sensitivity, nor cross-elasticity of demand in the broader market of all antibiotics," and the Court limited the relevant market to just cephalosporins. *Id*.

The Second Circuit has taken a similar view, holding that the brand name drug Coumadin and its generic alternative warfarin (one of the drugs specifically identified in the SSI) do not compete within the same product market. *Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 500 (2d Cir. 2004). If the generic drug warfarin, a blood thinner, is not even in the same product market as its brand name drug, then surely the government cannot fairly claim that warfarin is in the same product market as drugs, like carbamazepine that are used to treat entirely different conditions.³ And indeed, Teva is aware of no decision in which a court has ever recognized a product market as broad as the one claimed by the government here.

Given these circumstances, Teva is entitled to review the evidence the government presented to the Grand Jury to determine how the government defined the relevant market or markets that were supposedly corrupted by Teva, and how, if at all, the generic drugs it now seeks to rely upon were included as part of that market definition. That information will allow Teva to determine if a motion to dismiss one or more of the Counts is warranted based on the government's failure to identify a proper relevant market.

Other courts have found it plausible for a relevant market to consist of a brand name drug and its generic alternative. *See*, *e.g.*, *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680–81 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003). Significantly, the broadest relevant product markets involving drugs that courts have been willing to consider for antitrust purposes are still limited to only those prescribed to treat the same condition. *See*, *e.g.*, *Mylan Pharms*. *Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 436 (3d Cir. 2016) (affirming district court decision that relevant market consisted of all oral tetracyclines prescribed to treat acne).

B. Teva Has a Particularized Need to Determine Whether the Government's Alleged Conspiracies were Presented to the Grand Jury

The SSI alleged three distinct conspiracies limited to specific drugs. The government, however, now intends to prove an overarching conspiracy among the Counts that is not described anywhere in the SSI and that includes numerous drugs mentioned nowhere in the SSI. For example, Count One alleges that Teva, Glenmark, and Apotex coordinated to increase the price of pravastatin. Now the government says that Teva and Glenmark also conspired to increase the price of at least seven other drugs, including adapalene and nabumetone. The government also now alleges, for the first time, that while conspiring with Glenmark to fix the price of adapalene, Teva was also conspiring with Taro for the same purpose, and that while conspiring with Glenmark to fix the price of nabumetone, Teva was also coordinating with Sandoz.

There is nothing—in the 23 million plus records produced in discovery, or otherwise—to suggest that the government actually presented evidence of these newly identified conspiracies to the Grand Jury. And if the government actually presented evidence that Teva conspired to restrain trade in the newly identified drugs, and engaged in other conspiracies besides those charged in the SSI, then surely the government would actually have named those drugs and described those conspiracies in the SSI. But of course, the government did not do so, and instead appears to seek to expand and shift its theory against Teva, impermissibly after the return of the SSI. Teva needs to know whether the government actually presented evidence to the Grand Jury of these newly identified drugs and newly identified conspiracies so it has the opportunity to make appropriate and timely dispositive motions.

Only through a review of what the government actually presented to the Grand Jury can Teva assess the potential infirmities in the SSI's pleading of three distinct conspiracies, each with their own separate conduct. Where, for example, do each of the newly identified drugs supposedly

fit in those three charged conspiracies and what, if anything, was said to the Grand Jury about those drugs? Does the SSI unfairly lump all types of different alleged agreements as to different drugs into a single count? *See, e.g., United States v. Haddy*, 134 F.3d 542, 548 (3d Cir. 1998) ("Duplicity is the improper joining of distinct and separate offenses in a single count.").

These questions are even more concerning given the government's recent statements that appear to claim the existence of an overarching hub-and-spoke conspiracy with Teva at its center. Because of the sheer number of drugs as to which the government is now claiming it will present evidence, it is more than very likely that they all do not squarely fit into the framework of the SSI's current allegations. Respectfully, Teva is entitled to know how, if at all, these issues were addressed before the Grand Jury so it can bring an appropriate motion to dismiss if necessary, consistent with its rights under the Grand Jury Clause of the Fifth Amendment. *See, e.g., Sargent Elec. Co.*, 785 F.2d at 1128 (noting that the court "must determine whether there was a conspiracy aimed at a single relevant market or conspiracies aimed at several separate markets," and finding that "bid-rigging at different facilities constituted multiple Sherman Act offenses").

There is yet another problem here as well: the government's reliance on the newly identified drugs (and other yet unidentified generic drugs) could also create a constructive amendment of the SSI, in violation of Teva's constitutional rights. A constructive amendment occurs when "the evidence and jury instructions at trial modify essential terms of the charged offense in such a way that there is a substantial likelihood that the jury may have convicted the defendant for an offense differing from the offense the indictment returned by the grand jury actually charged." *United States v. Daraio*, 445 F.3d 253, 259–60 (3d Cir. 2006). A constructive amendment "is an exceptional category of error because it violates a basic right of criminal defendants, the grand jury guarantee of the Fifth Amendment." *United States v. McKee*, 506 F.3d

225, 229 (3d Cir. 2007). Allowing the government to introduce evidence about other generic drugs not specified in the SSI would, in effect, allow the government to prosecute Teva for antitrust conspiracies beyond those presented to the Grand Jury—a clear risk of constructive amendment.

United States v. Wozniak, 126 F.3d 105 (2d Cir. 1997), is particularly illustrative. There the Court found a constructive amendment and vacated the conviction when the jury was allowed to convict a defendant on the basis of marijuana transactions, but the indictment alleged only cocaine and methamphetamine transactions. Id. at 111. See also United States v. Zingaro, 858 F.2d 94, 103 (2d Cir. 1988) (finding a constructive amendment where the jury considered evidence of a loan not mentioned in the indictment as a basis for a RICO conspiracy conviction). Teva faces the same danger here; it could be convicted based on conduct relating to drugs different than the eleven actually identified in the SSI (and potentially the only ones that were the subject of Grand Jury evidence). For instance, the government could successfully convince the jury to convict Teva on Count One based on evidence that Teva conspired to fix the price of adapalene, despite the fact that the government never presented such evidence to the Grand Jury.

The "other generic drugs" language found in each Count of the SSI cannot be used as a placeholder to allow the government to include new drugs and different conspiracies into the case at its discretion.⁴ It would be no different than indicting a defendant on a charge of conspiring to

In its decision on Glenmark's Motion for Misjoinder and Severance, the Court noted that "the fact that the Government now intends to bring evidence of other generic drugs . . . is in line with the indictment" given the inclusion of the "other generic drugs" language in the SSI, and that there was "no likelihood that Glenmark would be found guilty of an offense different than the one charged." ECF No. 146 at 9–10 n.1. Not raised in that motion, however, was the unique nature of the antitrust violations charged here. As discussed above, antitrust law dictates that the government define the relevant product market(s) supposedly manipulated and identify the specific agreements reached as each product market. Allowing the government to introduce evidence of (and potentially obtain a conviction based on) other unspecified drugs is thus counter to this essential element of a Sherman Act violation.

fix the price of beef, yet allowing the government, by referencing "beef and other food" in the indictment, to rely on evidence the defendant fixed the price of oranges. The prosecutors drafting the SSI well knew how to identify specifically any drugs that were subject to the alleged conspiracies. Indeed, they did so in the SSI for eleven separate named drugs.

C. A Particularized Need Exists for the Relief Sought by Teva

Courts in the Third Circuit have ordered the disclosure of grand jury transcripts where the underlying circumstances demonstrated a particularized need. *See e.g., United States v. Breslin,* 916 F. Supp. 438, 440–441 (E.D. Pa. 1996) (disclosure of all grand jury testimony was warranted due to potential prosecutorial misconduct, including the possibility that the defendants were indicted on money laundering counts "not supported by any evidence presented to the grand jury"); and *United States v. Mahoney,* 495 F. Supp. 1270, 1277 (E.D. Pa. 1980) (ordering disclosure after the government failed to provide sufficient explanation of why the grand jury was only presented with witness interview summaries).

The government has provided no information as to what evidence it presented to the Grand Jury, if any, regarding the newly identified drugs. If the government had presented such evidence to the Grand Jury why wouldn't it say so? Similar to *Breslin*, it is likely the government is seeking to convict Teva on the basis of conspiracies that were not presented to the Grand Jury.

Teva is not on a fishing expedition and not seeking all grand jury transcripts to determine if there was some unspecified grand jury irregularity. *See United States v. Slade*, No. 12-0367, 2013 U.S. Dist. LEXIS 93382, at *4 (E.D. Pa. July 13, 2013) (Surrick, J.) (seeking "all" statements and exhibits presented to the grand jury); *United States v. Staton*, No. 10-800, 2012 U.S. Dist. LEXIS 79718, at *8 (E.D. Pa. June 8, 2012) (Surrick, J.) (defendant sought "an order compelling disclosure of the minutes and testimony of all matters occurring before the grand jury"). Rather, as stated above, there is a substantial basis to suspect a specific grand jury irregularity and Teva is

seeking a narrow set of grand jury materials to assess whether that irregularity is dispositive at least with respect to the newly identified drugs. *Cf. United States v. Minerd*, No. 08-2859, 299 Fed. Appx. 110, 111–12 (3d Cir. Nov. 14, 2008) (holding that a "vague allegation" of "fraud before the grand jury" is insufficient to justify disclosure of grand jury materials).

Teva's motion is readily distinguishable from the cases in which courts have denied motions for disclosure of grand jury materials. Teva has a clear particularized need. Because the SSI fails both to properly define the relevant markets that were the subject of the supposedly anticompetitive agreements and to disclose how the newly identified drugs (and those not even identified yet) even fit in those alleged agreements, there is a substantial likelihood that the SSI was "based on an improper theory" under antitrust law and is not "facially valid." *Cf. Chalker*, 2013 U.S. Dist. LEXIS 122018, at *18–19.

Further, unlike in *United States v. Tucker* and *Staton* respectively, Teva does not rely on mere "[s]uggestions of impropriety and speculation" or simply offer "unsupported belief and conjecture." No. 05-440-10, 2011 U.S. Dist. LEXIS 46003, at *6 (E.D. Pa. Apr. 27, 2011) (Surrick, J.); 2012 U.S. Dist. LEXIS 79718, at *14. Far from it, Teva has identified a "particular event or irregularity that took place" when the government seemingly failed to define an appropriate relevant product market and failed to identify all of the drugs as to which anticompetitive agreements were allegedly reached in the SSI. *Staton*, 2012 U.S. Dist. LEXIS 79718, at *12–13. As a result, Teva is entitled to review the evidence presented to the Grand Jury regarding the newly identified drugs to determine whether to bring a motion to dismiss for those significant reasons.

D. The Balancing of Interests Favors Teva's Narrow Request

Following a showing of particularized need, the Court "must weigh the competing interests and order so much disclosure as needed for the ends of justice." *Chalker*, 2013 U.S. Dist. LEXIS 122018, at *14 (quoting *Catania*, 682 F.2d at 62). The Court is afforded considerable discretion in balancing the interests of disclosure and secrecy. *Id.*; *see also United States v. Bunty*, 617 F. Supp. 2d 359, 372 (E.D. Pa. 2008) ("The decision to permit disclosure [of grand jury transcripts] is within the discretion of the trial court judge who must assess whether the need for disclosure overbalances the requirements of secrecy.") (quoting *Mahoney*, 495 F. Supp. at 1272). Teva's interest in the limited disclosure of evidence presented to the Grand Jury as to "other generic drugs" outweighs any claimed need for secrecy.

As discussed above, only through an examination of the Grand Jury minutes can Teva safeguard its constitutional rights and understand what evidence, if any, was presented concerning the other generic drugs and scope of the conspiracies of which the government claims those drugs were a part. That will in turn allow Teva to assess whether the SSI fails to allege sufficiently the relevant market(s) at issue, and whether the Grand Jury actually heard evidence concerning the numerous drugs sufficient to support their inclusion in agreements underlying the charged conspiracies. Moreover, this request is well defined and limited to the narrow particularized need identified above. *Cf. Slade*, 2013 U.S. Dist. LEXIS 93382, at *13 (denying defendants' motion to inspect grand jury minutes where defendants did not identify any portion of the indictment suggesting a charge made to the grand jury was erroneous).

With respect to any competing interests, Teva is not seeking the identities of any thirdparty witnesses who testified before the Grand Jury, only the evidence presented regarding the twenty-one newly identified drugs and any other generic drugs not identified in the SSI. Redaction of any witness identities, if necessary, can readily address any concern over the disclosure of witnesses who testified before the Grand Jury.⁵ Accordingly, Teva's request does not implicate any of the policies supporting grand jury secrecy. *See Douglas Oil*, 441 U.S. at 222. In addition, any such disclosure would be subject to the Protective Order already in place, and the Court could order any further restrictions it deems warranted (such as limiting review to attorneys).

Moreover, there is no reason to believe that the Grand Jury is still investigating Teva's conduct that allegedly occurred from 2013–2015, significantly outside any applicable statute of limitations. *See* 18 U.S. Code § 3282(a). Teva is unaware of any investigative activity currently ongoing and the government has not identified any such activity. The law is clear that "[t]he need for secrecy is lessened [when] the grand jury has completed its work." *United States v. Islam*, No. 20-cr-00045, 2021 U.S. Dist. LEXIS 18162, at *6 (E.D. Pa. Jan. 29, 2021). In short, there is also no reason to believe that the limited disclosure of the requested information would imperil any ongoing investigation.

Finally, should this Court have any remaining concerns with the secrecy of the requested Grand Jury minutes, it can undertake an *in camera* review of such evidence to address Teva's concerns, as the Court did recently in *Islam*. *See id*. at 3–5, 7 (*in camera* review was appropriate because the area of the law was in flux and the Grand Jury was necessarily required to draw fine distinctions in deciding whether to indict).

The government's interest in protecting the Grand Jury process is significantly diminished if the government solely presented law enforcement witnesses to the Grand Jury to testify about these issues. *See Dale v. Bartels*, 532 F. Supp. 973, 976 (S.D.N.Y. 1982) ("Reasons supporting secrecy where a private citizen testifies to the grand jury and thereafter there is no indictment, or the civilian witness does not testify at trial of a resulting indictment, do not in logic apply to a Government agent. A Government agent is not likely to be inhibited by subsequent disclosure in the sense that a businessman, victim of extortion or racketeering who testifies to the grand jury might be."). In discovery, the government has already produced numerous memoranda of interview and other documents identifying the law enforcement officers involved in the investigation, and Teva expects that these same law enforcement officers will testify at trial or otherwise be present.

V. <u>CONCLUSION</u>

For the foregoing reasons, Teva respectfully requests that, pursuant to Federal Rule of Criminal Procedure 6(e), the Court order the government to disclose, or allow inspection of:

the specific portions of any testimony or exhibits presented to the Grand Jury concerning the twenty-one newly identified drugs the government identified in its letter of April 27, 2021 and any other generic drugs not identified in the Second Superseding Indictment, redacted to remove the identities of any witnesses who testified before the Grand Jury.

In the alternative, the Court should order an *in camera* inspection of such evidence to allow the Court to consider the concerns with the Grand Jury presentation raised by Teva in bringing this motion.

Dated: April 1, 2022

Respectfully submitted,

Mark P. Ressler

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Attorneys for Defendant Teva Pharmaceuticals USA, Inc. **CERTIFICATE OF SERVICE**

I, R. Stephen Stigall, do hereby certify that I have served a true and correct copy of the

foregoing document upon all counsel/parties by electronic filing on April 1, 2022. This document

has been filed electronically and is available for viewing and downloading from the ECF system.

/s/R. Stephen Stigall
R. Stephen Stigall